K 122237

biophotas

JAN 0 3 2013

Traditional 510(k) Summary
As required in 21CFR 807.92, we hereby submit this 510(k) Summary:

510(k) owners name, address, phone, fax, contact person & prep date

The 510(k) owner is Biophotas, Inc., 250 El Camino Real, #114, Tustin, CA 92780

Phone: (714) 838 - 1956

Fax: (949) 606 - 8191

The contact person is Mr. Shepard G. Bentley, RAC

510(k) preparation date: 20 July, 2012

Name of the device, trade name, proprietary name, and classification name

Trade name: Biophotas LifeLight®

Common name: Infrared Lamp

Classification name: Lamp Infrared, Therapeutic Heating (ILY)

Predicate Device:

The legally marketed predicate for the Biophotas LifeLight® is:

K060792, illumiMed LED Phototherapy device

Device Description:

The LifeLight® is a lightweight device which uses specific wavelengths of light, produced by light emitting diodes (LEDs), to manage aesthetic conditions. LifeLight produces light in the near infrared region of the spectrum (880 nm) intended to provide topical heating to tissue. Blue light (464 nm) is intended to help reduce the appearance of mild to moderate acne.

Indication for Use/Intended Use:
The Biophotas LifeLight™ device is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum is intended to reduce mild to moderate inflammatory acne vulgaris.

The Intended Use information from the predicate product is equivalent and is reproduced below:

K060792 illumiMed LED Phototherapy device

The illumiMed™ device is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum is intended to reduce mild to moderate acne vulgaris. Use of the combination of blue, red and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate inflammatory acne vulgaris.

Technological characteristics:

The Biophotas LifeLight® is a lightweight, portable light-emitting diode (LED) device which emits light energy. A blue LED array in the 464 nm spectrum is used in treatment for mild to moderate inflammatory acne. The near infrared LED array provides mild topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle pain. The console of the device contains the electronics of the device and an automatic shut-off safety feature. The LifeLight operates for 30 minutes per use. The LifeLight shares substantially equivalent wavelengths to its predicate devices for the related indications, and substantially equivalent energy source, energy delivery, target populations and locations for use.

Technical Characteristic	Biophotas LifeLight®	illumiMed™
Wavelength	464nm, 640nm, 880nm	430nm, 660nm, 940nm
Electrical power	110 – 120 volts	110 – 120 volts
Treatment	Twice weekly, 30 minutes per treatment	Every three days, 9 minutes per treatment
Energy Delivery (standard dose)	465 nm - 19.6 Joules/cm2	430 nm - 18.9 Joules/cm2†
Energy Output	465 nm - 10.9 mW/cm2	430 nm - 35 mW/cm2
Indicated Use	Acne, Pain	Acne, Pain
Use	Prescription	Prescription

* = information taken from company user's manual †= information from predicate performance calculation

Nonclinical and clinical test data:

The Biophotas LifeLight® and the predicate devices have satisfied product safety testing to the IEC 60601-1 standard, and the electromagnetic safety testing to the IEC 60601-1-2 standard. Device testing to demonstrate the ability of the infrared LED array to elevate topical tissue temperature confirmed that the LifeLight elevated skin to a temperature of between 40 – 45 C measured over the course of ten minutes of treatment, during which mid-treatment readings the device was deactivated.

In summary, the BioPhotas LifeLight product is substantially equivalent to the predicate, utilizes mature technology and materials and provides a safe and effective addition to the substantial number of products cleared for these indications.

End of 510(k) Summary Section

Substantial Equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Biophotas, Incorporated
% Bentley Biomedical Consulting, LLC
Mr. Shepard G. Bentley, RAC
Director, Regulatory Affairs
250 El Camino Real #110
Tustin, California 92780

January 3, 2013

Re: K122237
Trade/Device Name: Biophotas LifeLight®
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY, GEX
Dated: December 14, 2012
Received: December 17, 2012

Dear Mr. Bentley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122237

Device Name: Biophotas Lifelight

Indications For Use: The Biophotas LifeLight device is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
The blue spectrum light is intended to reduce the appearance of mild to moderate acne vulgaris.

Prescription Use ___X__ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R Ogden
2013.01.02 16:11:27 -05'00'
(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ____K122237_____